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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,359	10/18/2001	James F. McGuckin JR.	1303 DIV CON	8570

7590

04/22/2004

Rex Medical, L.P.  
585 County Line Road  
Radnor, PA 19087

EXAMINER
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ROBERT, EDUARDO C

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/982,359

Applicant(s)

MCGUCKIN, JAMES F.

Examiner

Eduardo C. Robert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 56-80 is/are pending in the application.
- 4a) Of the above claim(s) 61-66, 68, 75 and 77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 56-60, 67, 69, 70, 72, 74, 76, 78 and 79 is/are rejected.
- 7) ☒ Claim(s) 71, 73 and 80 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 October 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3-5.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION*****Election/Restrictions***

Applicant's election without traverse of Invention I (claims 56-80) and Species II (Figures 6-28) in Paper No. 10 is acknowledged.

It is acknowledged that applicant believes all claims 56-80 read on the elected Species, i.e. Figures 6-28. It is noted that comparison of the claims with Figure 6-28 and the specification shows, however, that the species of Figures 6-28 does not have a surgical apparatus comprising an elongated housing with *a tissue piercing element extending from the housing* and a cutting loop and first and second support members advanceable from the channel to a second position as required in claims 61 and 62. It is noted that as shown and disclosed the cutting loop and support members would not work with a piecing member, e.g. 204 in Figure 6, extending from the housing. Furthermore, the species of Figures 6-28 does not have an electrocautery cutting wire *advanced* by the at least one support from a collapsed position to a second position as required by claims 63-66. It is noted that as disclosed the support members 206 function as guide for the expansion of the cutting wire 214, however, they do not advance, i.e. cause to move forward, the cutting wire. Moreover, the specification in page 19, lines 5-7, clearly states that the support catheters 212 move to the right in Figure 9 *advancing* tissue cutting wire loops 214 along the outer periphery of support members 204. Also, the species of Figure 6-28 does not have means *extending* from the housing for creating access to the tissue mass and cutting means advanceable from a collapsed position within the housing to an expanded position outside the housing and support means as required by claim 68. It is noted that this limitation is similar to

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the one of claims 61 and 62 explained above. Furthermore, claims 75 and 77 do not read on the elected Species for the same reasons claims 61, 62 and 68 do not read on the elected Species (see explanation above for claims 61 and 62).

Claims 61-66, 68, 75, and 77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.

The requirement is still deemed proper and is therefore made FINAL.

### ***Drawings***

The drawings are objected to because they do not include certain reference signs mentioned in the description. 37 CFR § 1.84(f) states, "Reference signs not mentioned in the description shall not appear in the drawing and vice versa." The following reference signs are not included in the drawings: "155", "150", 160", "27", "248". Correction is required.

The drawings are objected to because reference number "126" is not shown in Figures 7-8 as stated in the specification.

Furthermore, Figures 15-17 and/or 18-24 do not show what is described in page 17, lines 2-7 of the specification.

**A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.**

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### *Specification*

The specification is objected to because it does not include certain reference signs shown in the drawings. 37 CFR § 1.84(f) states, "Reference signs not mentioned in the description shall not appear in the drawing and vice versa." The following reference sign is not mentioned in the description: "224". Correction is required.

### *Claim Objections*

Claims 56-60 are objected to because of the following informalities: in claim 56, lines 7 and 9, "the target tissue mass" should be changed to -- the tissue mass -- to be consistent with line 1 of claim 56. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 56-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 56 there exists an inconsistency between the language in the preamble and that of the body of the claim, thus making the scope of the claim **unclear**. In the preamble, line 1, applicant recites "A surgical apparatus" with the tissue mass being only functionally recited, i.e. "for excising a tissue mass...", thus indicating that the claim is directed to the subcombination, "A surgical apparatus". However, in lines 8-9, applicant positively recites the tissue mass as part

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of the invention, i.e. "a tip of the first and second support members extending past the target tissue mass", thus indicating that the combination, surgical apparatus and tissue mass, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claim is intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claims 56-60 will be considered as being drawn to the subcombination, surgical apparatus.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 56, 57, 60, 67, 69, 70, 74, 76, and 78 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 30 of U.S. Patent No. 6,280,450. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the application claims and the patent claims lies in the fact that the patent claim includes more elements and/or is more specific. Thus the invention of the patent claim is in effect a "species" of the "generic" invention of the

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application claims. It has been held that the generic invention is “anticipated” by the “species”.

See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the application claims are anticipated by the patent claim, they are not patentably distinct from the patent claim.

### ***Claim Rejections - 35 USC § 102***

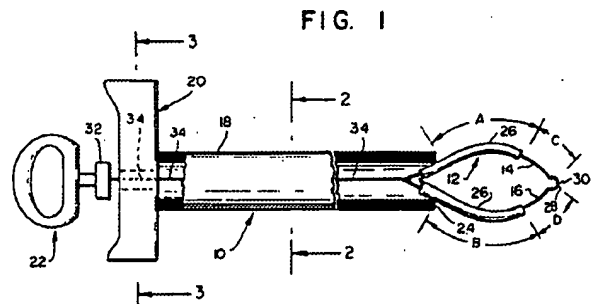
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 56, 59, 60, 74, 76, and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Doll (U.S. Patent No. 5,078,716).

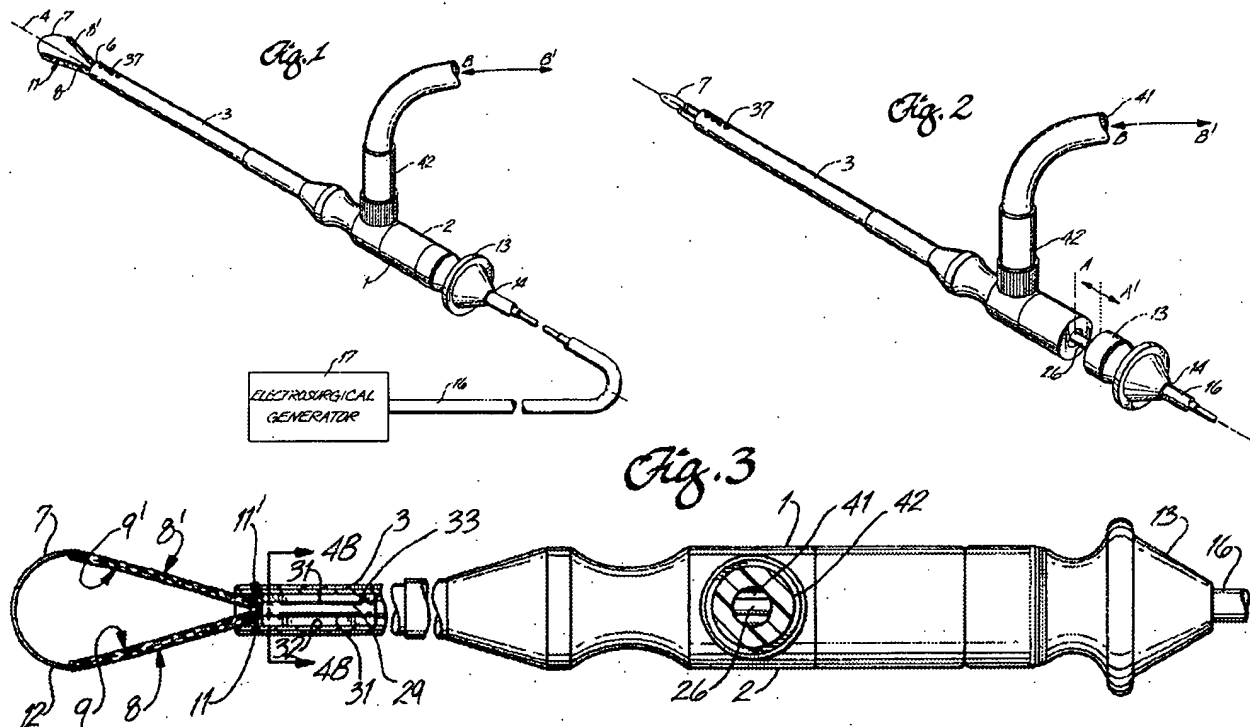
Doll discloses a surgical apparatus (see Figure 1) comprising an elongated housing 18 with a distal portion and a channel. The apparatus further comprises first and second support members 26 advanceable from the



channel to a second position (see Figure 1). The tip of the support members can extend past a target tissue mass. The apparatus also has a cutting loop formed by wires 14 and 16. The loop expands with the support members to a position that has a diameter exceeding a transverse dimension of the housing (see Figure 1). The loop is electrically energized to cut tissue, i.e. electrocautery wire. The support members spring biased to diverge radially and are advanced through an axial opening (see Figure 1).

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Claims 56, 59, 60, 67, 69, 70, 72, 74, 76, and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Munro (U.S. Patent No. 5,437,665).



Munro discloses a surgical apparatus comprising an elongate housing having a distal portion and a channel, e.g. trocar or cannula (see col. 4, lines 34-41). The apparatus further comprises a first and second support members 8 and 8' advanceable from the channel to a second position, shown in Figure 1 and 3. The tips of the first and second support members can extend past a target tissue mass. The apparatus also comprises a cutting loop 7 expandable by the diverging support members to a position wherein a diameter of the cutting loop exceeds a transverse dimension of the elongated housing (see Figures 1-3 and col. 4, lines 41-46). The loop is electrically energized to cut tissue, i.e. electro-surgical loop. The support members are spring biased (see Figure 3 and col. 4, lines 54-60).



***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Munro (U.S. Patent No. 5,437,665) in view of Hart et al. (U.S. Patent No. 5,853,374).

Munro discloses the claimed invention except for a membrane advanceable with respect to the elongated housing, i.e. trocar or cannula. Hart et al. discloses the using of a membrane or collection bag 10 advanceable with respect to a trocar or cannula 12 (see Figure 1, at right side). The purposes of the collection bag is to collect or remove tissue mass from the body without causing infection problems or other complication, e.g. leaving pieces of material at the site (see col. 1, lines 10-24). It would have been obvious to one skill in the art at the time the invention was made to construct the apparatus of Munro having a membrane or collection bag in view of Hart et al., in order to prevent that tissue mass is left by accident in the site of the procedure and/or to prevent possible complications, e.g. dropping the removed tissue mass.

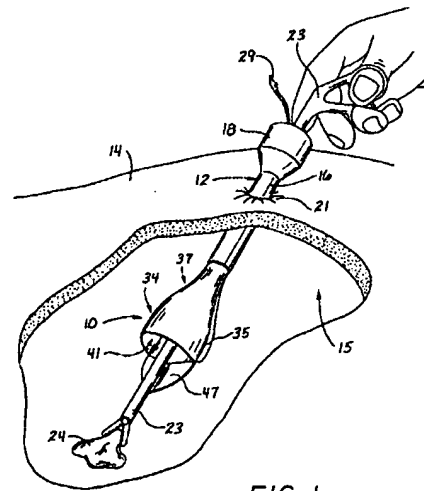


FIG. 1

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***Allowable Subject Matter***

Claims 71, 73, and 80 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 58 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

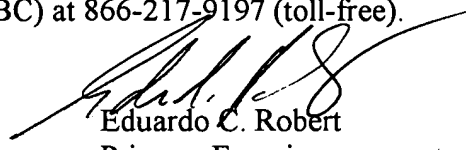
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703-308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eduardo C. Robert  
Primary Examiner  
Art Unit 3732

E.C.R.